

**AMENDMENTS TO THE DRAWINGS**

The attached Replacement Sheets of drawings for FIGS. 8A-8D are clearer copies than those believed to have originally be filed. No substantive changes or new matter has been added.

Attachment:        2 Replacement Sheets (Figs. 8A-8D)

## **REMARKS**

### **Status of the Claims**

Following entry of this amendment, claims 15-39, including two independent claims (numbers 15 and 28), are pending in this application. The Examiner has withdrawn claims 2-11, 13-27, 29, 30 and 33-39 and rejected claims 1, 12, 28, 31 and 32. By this amendment, claims 1 to 14 are canceled. Claim 28 has been amended. In addition, Applicants dispute below the Examiner's designation of claims corresponding the provisionally elected invention. Applicants election included claims 15 to 27, 29, 30, and 33 to 39, which have been withdrawn by the Examiner. Applicants explain below why these claims must be considered in this application.

No new matter is added by any of these amendments or additions. Upon entry of this amendment, claims 15 to 39 will be pending in this application with claims 15 and 28 being independent.

### **Drawings**

The Examiner objected to the drawings FIGS. 8A-8D stating that they are unclear and one could not understand what they show. The Examiner stated that they appear to be a photocopies of pictures, and that corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office Action to avoid abandonment of the application.

In response, Applicants attach hereto Replacement Sheets for FIGS. 8A-8D, which are clearer photocopies of the drawings previously filed, and are believed to be acceptable to the Examiner.

### **Specification**

Per the Examiner's direction, the continuing data section at the beginning of the specification has been amended to reflect the current status of the priority information.

**Claim Objections**

The Examiner objected to claim 12 as an improper dependent claim because it refers to itself. Applicant has cancelled claim 12, thereby obviating this objection.

**Election/Restriction Requirement and Designation of Claims**

Applicants continue to disagree with the Examiner's Restriction Requirement and, in particular, the Examiner's designation of claims corresponding to the provisionally elected species.

The Examiner made a 7 way restriction requirement in this case, requiring restriction from among 7 so-called species that correspond to embodiments disclosed in given figures of the application. The Applicant elected a species (the embodiment illustrated in Figures 8A-D and Figures 9 and 10 (right side)) having locking or detent elements, a partially cone shaped element, and flange surfaces configured to slide under pressure. Each of these features is described with respect to the right side of Figures 9 and 10 in the application (Species VII as denominated by the Examiner) and their interrelationship is noted:

In the **right hand embodiment** (and as **best seen in FIG. 9**), an outer surface 256 of closure flange 240 is angled outward (away from central longitudinal axis 228 and toward the proximal portion of anchor element 214) at an angle 260 of approximately 10 degrees. Where outer surface 256 is also curved in a plane transverse to central longitudinal axis 228 (see FIGS. 8C and 8D), **outer surface 256 is in the shape of a partial cone as best illustrated in FIG. 8C**. Side wall 224 includes a correspondingly angled inner surface 258, allowing cone shaped flange 240 to penetrate into anchor 214 upon closing of closure element 230. In addition, the angled nature of surfaces 256 and 258 allow more mass to be included in closure flange 240, making it stronger and more dimensionally stable, while the removal of mass or thinning of sidewall 222 allows for more resilience, and thus more displacement when such displacement is desired close to flange 232 inward while maintaining strength in lower parts of the sidewall.

The increase in angle from 15 to 45 degrees from the left hand embodiment to the right hand embodiment has a number of implications for an anchor assembly of the invention. One implication is that, since the contact area where flange surfaces 234, 242 meet is increased (and it is also increased as a result of cone angle 260), the stresses at

the surfaces are reduced. A further implication is that forces tending to draw sidewall inward will be increased due to the fact that the pressure in the contact area has been "aimed" inward, that is,  $\cos(RS)$  is larger. In addition, the configuration on the right hand embodiment with  $RS = 45$  degrees is such that, **when the flanges are loaded (by applying pressure to the spinal fixation element through closure element 230) and sidewall 222 is drawn inward, friction between surfaces 234 and 242 is overcome, allowing the flanges to slide with respect to each other** and resulting in sidewall 222 and anchor flange 232 being displaced inward as illustrated in FIG. 10. As shown in FIG. 10, where friction forces are overcome and flanges 232, 240 can slide with respect to each other, anchor flange 232 and at least a portion of sidewall 222 is displaced inward, securing closure element 230 within anchor element 214 and **causing locking elements 252, 254 (FIGS. 8A-8D) to more securely lock, resulting in a more permanent and secure fixation of the spinal fixation element to the anchor.** [Page 15, line 17 to Page 16, line 14.]

More specifically, in response to the Restriction Requirement dated March 16, 2005, Applicants traversed the Restriction to the extent that Species V (said by the Examiner to correspond to Figures 8A-8D) and Species VII (said by the Examiner to correspond to Figures 9 and 10 (right side)) are the same. In particular, the right side of Figures 9 and 10 illustrates one characteristic of the embodiment of Figures 8A to 8D – namely, the angle of the flange contacting surfaces. On that basis, Applicants elected Species VII (and Species V which is the same) and since all of the original claims 1-39 read on the species provisionally elected, none of the 39 claims should have been withdrawn.

In the outstanding Office Action, the Examiner made the election requirement final and withdrew claims 2-11, 13-27, 29, 30 and 33-39 from consideration – **leaving only 5 of the original 39 claims pending.** In response to Applicants' election and designation of claims, the Examiner asserts:

The traversal is on the ground(s) that the Species V and VII are the same. This is not found persuasive because the specification appears to indicate that the embodiment shown in the Figures 8A-8D (Species V) is a different one from the one shown in the embodiment of Figures 9 and 10, right [side]. The Species V is one wherein the outer surface is angled outward and also curved in a plane transverse to the central longitudinal axis, e.g. a partial cone, and the Species VII only has an angled outward outer surface as

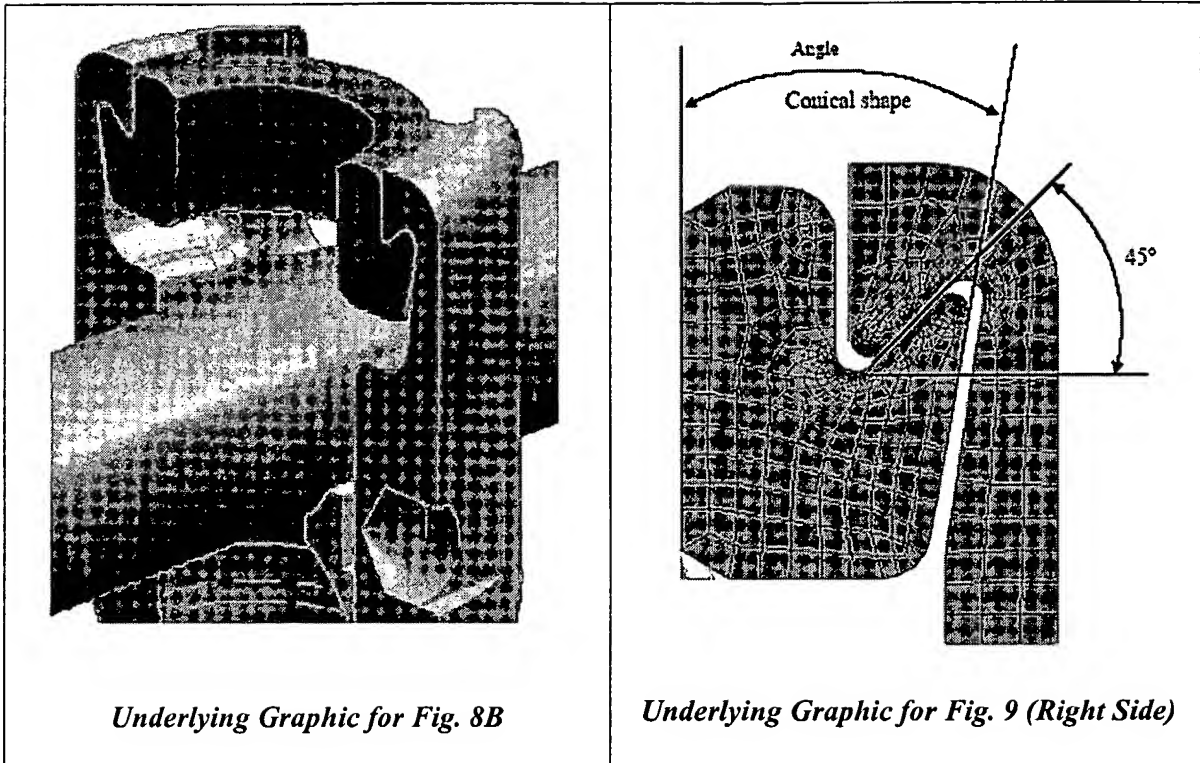
stated in applicant's specification page 15, lines 17-21. Moreover, the figures may look the same but they are not necessary the same. Also, Figures 8A-8D are so bad that one barely can understand what they are showing.<sup>1</sup> Thus, applicant's argument that Species V and VII are the same are not persuasive and the Species elected VII is considered to include only Figure 9 and 10, right size.

In fact, the Examiner is exactly wrong on the facts of the application. Replacement Figures that Applicants believe to be clearer than the copies seen by the Examiner are attached hereto. In addition, Applicants provide below side-by-side the underlying graphics that provide the basis for Figure 8B and the Figure 9 (right side) for the purpose of making clear what the figures show. There is no doubt, based upon the Figures and the text of the application, that the right side of Figures 9 and 10 illustrate a particular feature of the device of Figures 8A-D, namely the angled surfaces of the flanges that causes the flanges to slide upon loading – and that the text of the application clearly places this feature in the context of the embodiment of Figures 8A-D.

Referring now to the specific features provided in the embodiment provisionally elected by the Applicants (namely, (a) the partial cone shape, (b) the locking or detent elements, and (c) the flange surfaces configured to slide), it can readily be seen that these elements are all present in the embodiment elected and that the Examiner is mistaken in his assertions that they are not:

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<sup>1</sup> If the quality of the copy of the Figures available at the Patent Office is so poor, one cannot help but wonder why the Examiner did not require a cleaner copy *before* making a restriction requirement based solely on the Figures and basing a withdrawal of virtually all of the claims in the application based only on the Figures.



With respect to the partial cone shape of the right hand side of Figures 9 and 10, the Examiner says that:

The Species VII does not provide a partial cone shaped outer surface as required in claims 15-27, 29, and 30.

In contrast, the application specifically says at page 15, lines 17 to 21 that the right hand embodiment of Figures 9 and 10 does include the partial cone shape illustrated in Figure 8C:

***In the right hand embodiment (and as best seen in FIG. 9), an outer surface 256 of closure flange 240 is angled outward (away from central longitudinal axis 228 and toward the proximal portion of anchor element 214) at an angle 260 of approximately 10 degrees. Where outer surface 256 is also curved in a plane transverse to central longitudinal axis 228 (see FIGS. 8C and 8D), outer surface 256 is in the shape of a partial cone as best illustrated in FIG. 8C.***

With respect to the detent or locking elements of the right hand side of Figures 9 and 10, the Examiner says that:

It is noted that comparison of the claims with Figures 9 and 10 (right size) and the specification shows, however,

that the species of Figure 9 and 10 (right size) does not have detent elements as required in claims 2-10 and 33-37.

In contrast, the application specifically says at page 16, lines 9 to 14 that the right hand embodiment of Figures 9 and 10 does include the detents (or locking elements) illustrated in Figures 8A-D:

***As shown in FIG. 10***, where friction forces are overcome and flanges 232, 240 can slide with respect to each other, anchor flange 232 and at least a portion of sidewall 222 is displaced inward, securing closure element 230 within anchor element 214 and ***causing locking elements 252, 254 (FIGS. 8A-8D) to more securely lock***, resulting in a more permanent and secure fixation of the spinal fixation element to the anchor.

There is no doubt that all three of these features (namely, (a) the partial cone shape, (b) the locking or detent elements, and (c) the flange surfaces configured to slide) are present in the provisionally elected embodiment and that the features work together in a particularly useful configuration of this embodiment. Claims referring to these features are properly designated as corresponding to the provisionally elected embodiment.

The Examiner also asserts that claims 11, 38 and 39 are patentably distinct because they include the recitation of a centrally placed clamping member. The Examiner appears to base this on an unwritten (and contrary to law) requirement that each recited feature must appear in a single figure. As noted above, the embodiment illustrated in the right side of Figures 9 and 10 is a cross-sectional view of the embodiment of Figures 8A-D, intended to illustrate the effects of the angle of the radial slant on the ability of the flanges to slide. The embodiment of Figures 8A-D has a centrally placed clamping mechanism, and the threaded wall 244 for receiving that centrally placed clamping member. That threaded wall is provided in Figures 9 and 10 (it is the vertical wall on the left side of the cross-section), it just happens not to be labeled in Figures 9 and 10 because the specific character of that wall does not impact the illustrated slant angle – the centrally placed clamping member is important to this embodiment, however, as it provides the pressure that causes the flanges to slide and the detent elements to become more secure. There is no basis for considering these claims not to be related to the provisionally elected embodiment.

**Double Patenting**

The Examiner has rejected claims 1, 28, 31, and 32 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,755,829. In particular, the Examiner asserts:

Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the application claims and the patent claims lies in the fact that the patent claims include more elements and are thus much specific. Thus the invention of the patent claims are in effect a "species" of the "generic" invention of the application claims. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since the application claims are anticipated by the patent claims, they are not patentably distinct from the patent claims.

Pending claims 15 to 39 are not patentably indistinct from claims 1 to 15 of the prior patent. None of the prior claims recite, teach or suggest the partial cone shape or sliding flange segment elements that are present in claims 15 to 39. For the reasons stated below, in particular with regard to the rejection over Mellinger, these features provide significant patentable distinction.

**Claim Rejections Under 35 U.S.C. §102**

**Claims 1 to 14:**

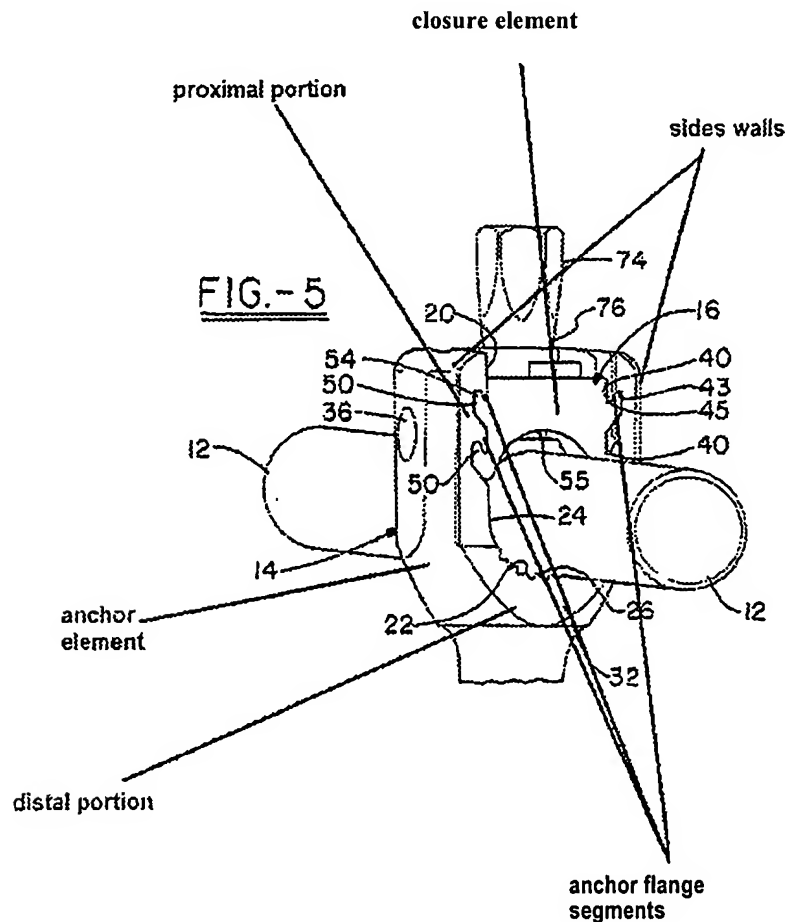
The Examiner has rejected claim 1 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,077,262 (Schlapfer et al.).

Applicants have canceled claims 1 to 14 herein without prejudice to presenting those claims in a future application.

**Claims 28 to 39:**

The Examiner has rejected claims 28 and 31 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,302,888 (Mellinger et al.). In particular, the Examiner asserts:

Mellinger et al. disclose an anchor assembly comprising an anchor element, e.g. 14 or 14' (see Figures 5-7). The anchor element defines a central longitudinal axis and having an open slot, side walls on opposed sides of the open slot, a proximal portion, a distal portion, and an anchor flange segment extending from each of the side walls in a direction toward the central longitudinal axis (see for example Figure 5 below).



The anchor flange segments each includes an inferior contact surface (see Figure 5 above) extending in a direction toward the central longitudinal axis and toward the distal portion defining a radial slant. The assembly further includes a closure element (see Figure 5 above) including a closure body and a plurality of closure flange segments extending from the closure body in a direction that is transverse to the anchor element central longitudinal axis (see Figure 5 above). Each of the closure flange segments includes a superior contact surface extending in a direction away from the central longitudinal axis and toward the proximal portion of the anchor element at the

radial slant. **The radial slant are configured to permit sliding of the anchor flange segments with respect to the closure flange segments.**<sup>2</sup>

**With regard the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Mellinger et al. which is capable of being used as claimed if one so desires to do so.** *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather **it is only necessary that the claims under attack "read on" something in the reference.** *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

The Examiner apparently recognizes that Mellinger does not disclose, teach or suggest the recitation in the claim that:

the **radial slant is configured to cause sliding** of the anchor flange segment inferior surfaces with respect to the closure flange segment superior surfaces **upon pressure being applied on the fixation element.**

In lieu of finding a teaching in the prior art, the Examiner (1) calls important feature of the recited device an "intended use," and (2) implies that the claims read on Mellinger even though Mellinger does not have this feature.

Mellinger does not anticipate claim 28 for at least two reasons. First, Mellinger suggests the opposite of the claim recitation. The claim specifically calls for the radial slant between the flange segments to be configured to cause sliding between the flange segments when the closure is loaded. What Mellinger actually says about its "dovetails" is the following:

The closure member includes multiple mating flange-like projections on each side or "dovetails" which have a corresponding configuration. These mating dovetails **inhibit the spreading or splaying** of the side walls of the channel in response to forces executed on the anchor assembly by the locking set screw acting on the stabilizer rod. . . . Multiple dovetails of the present invention **inhibits the anchor from spreading** in response to the

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<sup>2</sup> This statement does not correspond to the claim recitation. The claim states that the "radial slant is configured to cause sliding of the anchor flange segment inferior surfaces with respect to the closure flange segment superior surfaces **upon pressure being applied on the fixation element.**"

applied force. [Column 2, lines 3 to 9 and lines 58 to 60.]

Mellinger's dovetails are designed to hold still against spreading or splaying under loading. Holding still under loading is the opposite of sliding under loading. Mellinger not only does not disclose, teach or suggest the claim recitation, it discloses, teaches and suggests the opposite of the claim recitation.

Second, the claim recitation in question is not an "intended use." Rather, it is an important property of the claimed structure. The application makes clear that this property can be achieved only by calculating the load forces and designing the Radial Slant angle so that, under loading, the radial inward force overcomes the force of friction between the flanges. This is not one angle, but one that depends upon factors that include, for example, the material used to make the components. A device having flanges made from titanium will have a different coefficient of friction than a device having flanges made from stainless steel, and so the structures of the two devices will be different in order to provide the recited property. This is clearly explained in the application at page 16, lines 21 to 29:

It should be understood a person skilled in the art that the specific angles used in the embodiments of FIGS. 9 and 10 can be varied within the scope and spirit of the invention. For example, these embodiments are formed (both closure 230 and anchor 214 elements) from Titanium (the coefficient of friction for Titanium on Titanium being approximately 0.15) and for typical loadings applied to spinal fixation elements, and the above testing shows that 15 degrees of radial slant does not allow the friction forces to be overcome while 45 degrees of radial slant does. A person of ordinary skill in the art can determine specific angles of radial slant useful for particular configurations, materials, and loading forces using finite element analysis tools commonly used in the art.

Claiming a structure under these circumstances according to its properties (slides upon loading) is entirely appropriate and even preferable. The Court of Appeals for the Federal Circuit explained this concept in *E.I DuPont De Nemours v. Phillips Petroleum Co.*, 849 F.2d 1430, 1434-35; 7 USPQ2d 1129 (Fed. Cir. 1988):

Claim 1 includes this limitation: "when in the form of a film, an Elmendorf tear strength in the range of 150 to 400 grams per mil." Claim 12, which claims the copolymer in the form of pipe, recites a limitation to impact strength in terms of hoop stress. . . .

Phillips asserts, citing Titanium Metals Corp. of America v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed.Cir. 1985), that the strength limitations of claims 1 and 12 are merely property limitations that cannot serve to distinguish the claims from the Witt and Leatherman copolymers. In Titanium, the claims covered, for example, a "titanium based alloy consisting essentially by weight of about 0.6% to 0.9% nickel, 0.2% to 0.4% molybdenum, up to 0.2% maximum iron, balance titanium, said alloy being characterized by good corrosion resistance in hot brine environments." The reference upon which both the Patent Office and the court based their § 102 rejections showed an alloy with those percentages, and the court stated:

Congress has not seen fit to permit the patenting of an old alloy, known to others through a printed publication, by one who has discovered its corrosion resistance or other useful properties, or has found out to what extent one can modify the composition of the alloy without losing such properties. Id., 778 F.2d at 782, 227 USPQ at 778.

*Titanium, however, does not mean that property limitations can never have meaning in a claim. On occasion . . . structure alone may be inadequate to define the invention, making it appropriate to define the invention in part by property limitations. . . .*

It is clear, therefore, that the district court correctly regarded the claimed interpolymers as compositions that **can be permissibly defined in terms of structure and properties**. Thus, the issue is not, as in Titanium, whether one can get a patent on discovering a new property of an old composition of matter. **The issue is whether the claimed copolymer, as defined in part by various property parameters, is new.**

In this application, the flanges being configured to slide upon loading is new – the cited prior art reports exactly the opposite result of holding still or inhibiting motion upon loading. In addition, the specific angle of radial slant that produces this result depends on features such as the material that the flanges are made from and their coefficients of friction – a person of ordinary skill in the art can readily compute what the angle should be for a given device, but the angle may vary from device to device. Accordingly, claim 28 is appropriately limited as recited and claim 28 and the claims that depend therefrom are patentable over the cited reference.

Claims 15 to 27:

Each of these claims was incorrectly withdrawn from consideration by the Examiner. Upon their reconsideration, it will become clear that they are patentable over all of the references of record. In particular, independent claim 15 recites:

the closure flange segments further include exterior surfaces that extend away from the longitudinal axis and proximally when the closure element is placed in the open slot to provide a **partial cone shaped outer surface** to the closure flanges

No references of record disclose, teach or suggest this feature, or its advantages (which are detailed in the quotations from the application provided above). Accordingly, claims 15 to 27 are patentable for at least this reason.

Claim Rejections Under 35 U.S.C. §103

The Examiner has rejected claim 32 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,302,888 (Mellinger et al.). In particular, the Examiner asserts:

Mellinger et al. disclose the claimed invention except for the radial slant being at an angle of approximately 45 degrees to the central longitudinal axis. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the assembly of Mellinger et al. with the radial slant being at an angle of approximately 45 degrees to the central longitudinal axis, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

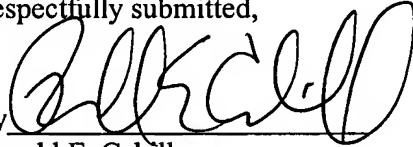
A radial slant of approximately 45 degrees is in no way an optimization according to Mellinger. In order for it to be an optimization, a person of ordinary skill in the art would have to understand the result achieved as optimal. In this case, Mellinger teaches that the goal is to inhibit motion upon loading – while the claimed device is expressly configured to slide upon loading. Claim 32 in no way provides an optimization of Mellinger, it provides the opposite of Mellinger. Mellinger expressly teaches away from the claimed result. Accordingly, Mellinger in no way renders claim 32 unpatentable.

**REQUEST FOR TELEPHONIC INTERVIEW**

Applicants believe that further prosecution of the pending application will best be served by a telephonic interview between the Examiner and Applicants' representative. Undersigned counsel for the Applicants will telephone the Examiner to arrange an appropriate time for the interview.

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Respectfully submitted,

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